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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/627,321	07/27/2000	Ludger Dinkelborg	SCH 1718 C1	2532

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EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT	PAPER NUMBER
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1762

DATE MAILED: 05/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/627,321

Applicant(s)

DINKELBORG ET AL.

Examiner

Jennifer Kolb Michener

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 1-14, 17-27, 36-39, 42 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15, 16, 28-35, 40, 41, 43 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION***Election/Restrictions***

1. Examiner acknowledges Applicant's amendments to claim 18 to overcome the 35 U.S.C. 101 rejections, discussed below. In addressing the 35 U.S.C. 101 concerns, Examiner stated that for the purposes of examination, she would examine claim 18 as a method of coating a stent with the substances listed in the claim. However, upon amending claim 18, Applicant has claimed a method of treating restenosis comprising implanting the stent. This class of invention is unrelated to the group containing claims 15 and 16 and to the other groups outlined in the restriction of Paper 8 on July 30, 2002 because the inventions are not disclosed as capable of use together and have different modes of operation, function, and effects. A method of implanting a stent is distinct from a method of coating one. For all the reasons outlined in Paper 8, this restriction is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 18, 36-39, 42, and 45 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 101

2. The rejection of claim 18 under 35 U.S.C. 101 has been withdrawn based on Applicant's amendments.

Claim Rejections - 35 USC § 112

3. The rejections of claim 16 under 35 U.S.C. 112, second paragraph, have been withdrawn based on Applicant's amendments.

Based on Applicant's amendments, the following new rejections are made:

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 15, 16, 28-35, 40-41, 43-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The terms "non-radioactive" and "non-pharmacophor" in claims 15 and 16 appear to be new matter.

Likewise in claims 40 and 41, the limitation requiring the radioisotopes to be bound in a non-covalent manner appears to be new matter.

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Additionally, in claims 43 and 44, the limitation requiring the radioisotope to *not* be P-32 appears to be new matter.

There does not appear to be support, in the originally-filed disclosure, for the newly-added limitations above.

Examiner has carefully reviewed Applicant's arguments made in anticipation of such a new matter rejection, as concerning the terms "non-radioactive" and "non-pharmacaphor", however, these arguments are not found persuasive.

Applicant argues that literal support for new limitations is not required if the specification would have conveyed to one having ordinary skill in the art that the appellant had possession of the concept. Applicant provides examples of adhesives used, which are, in fact, non-radioactive and non-pharmacaphor.

However, Examiner disagrees with Applicant's analysis.

The originally-filed disclosure would not have conveyed to an ordinary artisan that the Applicant had possession of the concept of such an adhesive. While the disclosure provides some examples of adhesives which are non-radioactive and non-pharmacaphor, these are merely exemplary. Applicant does not have support for claiming all such adhesives, in other words, Applicant does not have support for claiming every adhesive that is non-radioactive and non-pharmacaphor.

Examiner notes also that Applicant teaches, throughout, the use of gold as an adhesive and as a radioactive isotope useful in coating stents. The disclosure does not convey to an ordinary artisan that the use of the radioactive form of gold is excluded when selecting gold as the adhesive, as required by Applicant.

Claim Objections

6. Claims 30, 31, 34, 35, 38, and 39 are objected to because of the following informalities:

Examiner suggests alternate language be used for clarity in the above claims. For example, in claim 30, the phrase "in combination with a thiol-group-containing complexing agent" is not clearly associated with just gold. The phrase "said gold used in combination with a thiol-group-containing complexing agent" would make clear that the thiol limitation was limited to describing gold. On the other hand, if the thiol limitation is meant to describe the peptide, fat, and the gold, then the phrase "said peptide, fat, or gold used in combination...." would be clearer.

Similar language can be used in the other listed claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The rejection of claim 18 under 35 U.S.C. 102(b) as being anticipated by Fischell et al. (US 5,722,984) has been withdrawn in light of the withdrawal of this claim from consideration.

8. The rejection of claim 18 under 35 U.S.C. 102(b) as being anticipated by Armini et al. (US 5,919,126) has been withdrawn in light of the withdrawal of this claim from consideration.

Claim Rejections - 35 USC § 103

9. The rejection of claim 15 under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (US 5,722,984) has been withdrawn in light of Applicant's amendments. Examiner notes that the amendment limitations have been rejected as containing new matter. Upon removal of these limitations, this rejection would necessarily be reinstated.

10. Claims 16, 32, 41, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armini et al. (US 5,919,126).

Examiner maintains the rejection of claim 16 until such time as the foreign priority documents are supplied. The adhesives of Armini do not appear to be radioactive or pharmacophor-containing.

Newly added claims 32, 41, and 44 are added to this rejection.

Regarding claims 32 and 44, Armini teaches the use of sulfur-35 as the radioactive isotope.

Regarding claim 41, the radioisotopes of Armini do not appear to be bound covalently.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



Jennifer Kolb Michener
May 7, 2003



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